

REMARKS

Amendments to the Claims

Claims 1 and 8-18 are under examination with entry of the present Amendment. Claims 16-18 are cancelled without prejudice. Claims 1, 11 and 12 have been amended. No new matter has been added with the amendments made herein. Support for the amended claims is found throughout the application and in the as-filed claims. Applicants believe that the amended claims better define the invention in a manner supported by the original application, and in a manner so as to render moot the rejections as set out in greater detail below.

Rejections under 35 U.S.C. §103

The Office Action rejects claims 1, 10, 11, 15 and 16-18 as being unpatentable over U.S. Patent No. 5,776,887 to Wibert *et al.* The Office Action states that Wibert *et al.* discloses a composition containing the claimed ingredients as in claims 1, 10, 11 and 15:

The carbohydrate content is seen to have been more than 50% as in claims 1, 10 and 11 because rolled oats, which are a complex carbohydrate with a low GI is used in predominant amounts and the reference discloses 62% carbohydrates (col. 8, lines 40-60). Also, the GI is seen to have been within the claimed amounts of 1, 10, 11 and 15, due to the use of complex carbohydrates absent a showing to the contrary. Therefore, it would have been obvious to use known ingredients and known amounts of COH and a GI absent a showing to the contrary.

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As to claim 17, Wibert *et al.* disclose the composition in the form of a granola bar which is for humans (col. 8, lines 35-60). Therefore, it would have been obvious to administer a composition containing complex carbohydrates to humans.

Applicants respectfully traverse this rejection. This amendment is accompanied by a Declaration, under 37 C.F.R. §1.132, from Mr. Saul Katz. Applicants request entry and consideration of this Declaration. The Declaration is included to establish the distinctions between Applicants' claimed invention and the cited prior art compositions from the perspective of one skilled in the art of nutraceuticals and functional foods.

As stated in the Declaration, prior art formulations have generally reduced the glycemic index of a food by lowering the total carbohydrate content and increasing the fat or protein content. Replacing carbohydrates with fats is not a feasible option, particularly due to their high caloric content per gram. Increasing protein content tends to result in an unpalatable food item since popular proteins (for example, soy, whey, protein powders) have undesirable aftertastes.

Applicants' invention is based on the discovery that a food item having both a low glycemic index and an uncharacteristically high carbohydrate content sustains blood glucose levels in healthy humans, and provides a nutritious snack with singularly good taste and texture. The patentability of Applicants' invention lies in the combination of a low glycemic index and a high carbohydrate content in a specified relationship. The combination of the claimed low glycemic index lower than 35(50) and the claimed high carbohydrate content of greater than about 45% achieves the unexpected result of a low glycemic index without compromising the nutritional value, taste or texture of the food item. Applicants' claims require both of these features. Applicants have excluded the prior art since independent claim 1 recites a food item having a glycemic index "lower than 35(50)" and a total carbohydrate content "greater than about 45% by weight." Claim 1 thus requires a glycemic index lower than 35(50), a range not disclosed by the prior art as discussed in the Declaration.

In supporting Applicants' contention of non-obviousness, the Declaration attests to the success of the commercialized embodiment of the claimed invention. The SoLo GI™ low glycemic bars are commensurate in scope with the claims of the present application, hence comply with MPEP §716.03(a). The features of low glycemic index and high carbohydrate content which are responsible for the commercial success of the SoLo GI™ bars are recited in the independent claims. This embodiment of the claimed invention received an award for innovation in the nutrition industry, and is currently being used as the benchmark low GI product in five major independent clinical trials conducted by leading scientific institutions including the National Institutes of Health, Children's Hospital Oakland Research Institute, Children's Hospital Boston, Harvard Medical School and Fred Hutchinson Cancer Research Center. Repeat sales across the United States are indicative of

consumer satisfaction and the merit of the commercialized embodiment (see http://www.solo-gi.com/products_main.html). If it had been obvious to develop a low glycemic index, high carbohydrate food item, others would certainly have reported it in the literature or commercialized such a product. Clearly, the prior art had not arrived at Applicants' claimed invention because the combination is not obvious.

To establish a *prima facie* case of obviousness, the prior art reference must teach or suggest all the claim limitations. The Declaration states that Applicants' claimed invention has a glycemic index lower than the theoretical GI of the granola bar of Wibert *et al.* Applicants' claim 1 explicitly recites a "glycemic index lower than 35(50)." The granola bar of Wibert *et al.* was found to have a theoretical glycemic index as low as 46.5 or as high as 64.7 – outside of the range – as calculated in Table 1 of the Declaration. Wibert *et al.* does not teach or suggest that a glycemic index lower than 35(50) combined with a high carbohydrate content is desirable or results in beneficial properties for a food item. In view of the Declaration submitted herewith and with reference to the claim language, Applicants submits that the claimed invention is distinct from that of Wibert *et al.*

Further, Applicants respectfully disagree with the Examiner's comment that Wibert *et al.*'s "carbohydrate content is seen to have been more than 50% as in claims 1, 10 and 11 because rolled oats, which are a complex carbohydrate with a low GI is used in predominant amounts and the reference discloses 62% carbohydrates." Traditionally, it was thought that complex carbohydrates (breads, cereals, legumes and starchy vegetables) were slowly digested and absorbed into the bloodstream, while simple carbohydrate (sugars, honey) were assumed to be rapidly absorbed and capable of raising blood sugar faster than complex carbohydrates. People with diabetes were thus advised to eat mainly complex carbohydrate and limit their intake of foods high in simple carbohydrate.

However, the glycemic index developed by Jenkins *et al.* has proven this conventional thinking to be erroneous. The glycemic index is a method which provides a reliable scientific means of classifying carbohydrate foods. Some foods with a relatively high content of simple

carbohydrates (e.g., those in milk and fruits) have lower GI values than many foods which have mainly complex carbohydrates (e.g., potatoes and rice). The glycemic index enables testing of a single food item (for example, a type or species of apple) or a mixed food item (for example, a nutrition bar).

The Wibert *et al.* reference does not provide sufficient description of the oats used. Applicants emphasize that not all oats are low GI, as rolled oats have been de-hulled, rolled with steam rollers to flatten them out, re-steamed and toasted; being treated for fast or instant cooking – which also results in instant digestion (most are high GI). In contrast, steel-cut oats are the whole grain kernel (sometimes labeled as oat groats or traditional porridge oats) that have been cut, not rolled or pounded, and take longer to cook but maintain their oat structure, which slows digestion, helping to keep blood sugar levels stable (low GI). Steel cut oats start with the whole grain kernel – meaning the unadulterated bran, germ and endosperm, where all the nutrition is; then are cut into small pieces with steel blades and left unrolled so they look like little granular nubs of brown rice. The GI value of traditional porridge oats is approximately 51, whereas dehulled oat flakes can have GI values ranging from 50 to 80, depending on the source and degree of processing (Foster-Powell *et al.*).

Another example is the potato which was previously thought to be a complex carbohydrate and recommended to diabetics for controlling blood sugar; however, GI research has shown that most potatoes (depending on the source, type and preparation method) have high GI values and can raise blood sugar faster than table sugar. For example, baked potatoes can have GI values ranging from 56 to 111, instant mashed potatoes from 74 to 97, mashed potatoes from 67 to 91, and French fried potatoes at approximately 75.

As indicated by the above oat and potato examples, there is a great inequality in the extent to which different carbohydrate sources raise the blood glucose. Further, differences are observed between and within most food groups. Simple carbohydrate exchange lists based on chemical analysis do not predict the physiological response or effect of foods, as conventionally thought. This

is the primary reason why Jenkins *et al.* developed the glycemic index and its measurement using validated protocols (i.e., measuring the area under the curve in comparison with a standard selected from glucose or white bread).

The glycemic index is a scientifically tested and clinically validated method for obtaining an accurate measure of the final glycemic index of a food item, and for determining with accuracy the effect of the food item on blood sugar. Jenkins *et al.* indicated that the glycemic index numbers of each ingredient contained in a food item cannot be simply added together. A large amount of a single ingredient allegedly having a low glycemic index cannot be used to determine or predict the glycemic index of a food item as a whole. The GI measurement of a mixed food will vary significantly based upon the type (white rice (high GI) vs. Basmati rice (much lower GI due to high amylose content that resists gelatinization); form of processing of the carbohydrates (i.e. oats and potato); ripeness (fruit); preparation (heated, steamed); physical form (other than original state – mashed, crushed); and the particular amount and combination of protein and fat with which they are digested. The results of the Jenkins *et al.* study clearly emphasized the need for the glycemic index and standardized testing methods to demonstrate with certainty the effect of a food item on blood sugar.

The impact of Applicants' food item on blood sugar was scientifically tested and clinically validated in this manner. The Wibert *et al.*, Sunvold and Nidetch references do not disclose any level of glycemic index testing. As previously discussed, prior art formulations have generally reduced the GI of a food by lowering the carbohydrate content and increasing the fat or protein content. Replacing carbohydrates with fats is undesirable due to their high caloric content per gram. Increasing protein content results in an unpalatable food item, and overconsumption can result in protein toxicity and acceleration of kidney disease. Low carbohydrate diets (for example, the Atkins diet) have been vigorously condemned by the scientific community (including the American Medical Association and American Heart Association) as increasing the risk of ketosis, stroke and heart disease. Applicants' food item has both a low glycemic index and a high carbohydrate content for sustaining blood sugar and providing a nutritious snack with good taste and texture. Applicants'

food item displays dual benefits – provision of health-promoting carbohydrates and avoidance of excessive blood glucose peaks which are detrimental for weight loss and disease prevention. Applicants' food item, developed in accordance with pioneering GI research which replaced conventional knowledge of carbohydrates, is thus distinct from the prior art. Reconsideration and withdrawal of this rejection are respectfully requested.

The Office Action rejects claims 1, 8, 10 and 11 as being unpatentable over U.S. Patent No. 6,458,378 to Sunvold. The Office Action states that Sunvold discloses a composition as in claim 1 for improving glucose metabolism in animals by controlling the insulin response, which contains a source of protein, fat and carbohydrates. The Office Action states that:

The carbohydrates in the food item are greater than 45% by weight. Grains are not considered to be rapidly absorbed carbohydrates, since they contain a lot of fiber, which keeps the carbohydrates from being rapidly absorbed (col. 8, lines 35-60). Claims 1, 8, 10 and 11 differ from the reference in the particular glycemic index (GI). Sunvold discloses the use of a composition containing grains, which is seen to have produced a composition with a GI lower than 50 since grains are used in the composition and no simple sugars or sucrose. Therefore, it would have been obvious to make a composition using the claimed ingredients.

Applicants respectfully traverse this rejection. Claim 1 explicitly recites a "glycemic index lower than 35(50)." The pet food composition of Sunvold was found to have a theoretical glycemic index as low as 55 or as high as 65 – outside of the range - as calculated in Table 2 of the Declaration. Thus, the language of Applicants' claim 1 clearly distinguishes the teachings of Sunvold. As required for an obviousness rejection, Sunvold fails to teach or suggest all Applicants' claim limitations, namely a low glycemic index combined with a high carbohydrate content. Reconsideration and withdrawal of this rejection are respectfully requested.

The Office Action rejects claims 9 and 15 as being unpatentable over Sunvold as applied to the above claims, and further in view of Wibert *et al.* Since rejected claims 9 and 15 are ultimately dependent upon claim 1, which Applicants believe patentably distinguishes over all cited prior art, there is respectfully no basis for the §103 rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

The Office Action rejects claim 1, 10, 11, 13 and 14 as being unpatentable over Nidetch (Weight Watchers, pages 218-219). The Office Action states that Nidetch discloses a composition containing protein, fat and carbohydrates where the total carbohydrate content is more than 45% as in claims 1 and 10:

Casein is the major protein found in cheddar cheese and skim milk as in claim 14. The claims differ from the reference as to the particular GI. However, the GI is seen to have been less than 40 as in claims 1, 10, 11 and 14 and less than 35, as in claim 13 since the composition has been shown (pages 218-219). Therefore, it would have been obvious to make a composition containing the claimed ingredients and glycemic index.

Applicants respectfully traverse this rejection. The Declaration states that Applicants' claimed invention has a glycemic index lower than the theoretical GI of the cheddar cheese muffin of Nidetch. Claim 1 explicitly recites a "glycemic index lower than 35(50)." The cheddar cheese muffin of Nidetch was found to have a theoretical glycemic index as low as 53.5 or as high as 63.5 – outside of the range - as calculated in Table 3 of the Declaration. As required for an obviousness rejection, Nidetch fails to teach or suggest all Applicants' claim limitations, namely a low glycemic index combined with a high carbohydrate content. Applicants' claims require both of these features. Thus, the language of Applicants' claim 1 clearly distinguishes the teachings of Nidetch. Reconsideration and withdrawal of this rejection are respectfully requested.

The Office Action rejects claim 16 as being unpatentable over Sunvold in view of Wibert *et al.* and further in view of Foster-Power International Table of Glycemic Index. In the interest of advancing prosecution and without acquiescing to this rejection, Applicants have cancelled claim 16 without prejudice. In view of Applicants' amendments, this rejection is considered moot.

Applicants submit that it is improper to reject any of these claims under 35 U.S.C. 103(a). A *prime facie* case of obviousness has not been established. In summary, claims 1 and 8-15 are not anticipated or rendered obvious in view of the cited prior art since the references do not teach or suggest the features of the invention as claimed. Withdrawal of all claim rejections under 35 U.S.C. §103 is thus respectfully requested.

This amendment is accompanied by a Declaration from Saul Katz. Applicants respectfully request entry and consideration of this Declaration under 37 C.F.R. §1.132. The Declaration is included to establish that there are distinctions between Applicants' claimed invention and the cited prior art.

CONCLUSION

This Amendment is accompanied by a Request for Continued Examination, the fee in the amount of \$405.00, and a Declaration Under 37 C.F.R. §1.132, with attachments.

In view of the foregoing remarks and amendments, it is respectfully submitted that this application is in condition for allowance and allowance thereof is respectfully requested. If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

Respectfully submitted,

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